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| EXAMINER | |
|---|---|
| NATARAJAN, MEERA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1643 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,903 | HITOSHI ET AL. | |
| | Examiner | Art Unit | |
| | Meera Natarajan | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *23 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,36-41,43 and 44* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/28/2007 and 07/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendments and Arguments*

1. Claims 23 and 36-44 are pending.

2. Claims 1-22 and 24-35 have been cancelled by Applicant.

### *Withdrawn Objections*

3. The objections to Claim 23 are withdrawn in light of the Applicants' amendments to the claim.

### *Withdrawn Rejections*

### *Claim Rejections - 35 USC § 112*

4. The rejection of claims 23 and 36-44 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendments to the claims.

5. The rejection of claims 23 and 36-44 under 35 U.S.C. 112 first paragraph, as failing to comply with the enablement requirement has been withdrawn in light of Applicants' amendments to the claims.

### *Rejections Maintained*

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of claims 23 and dependent claims 36-41, 43 and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Applicants assert the disclosure of the sequences of FANCA along with a percent identity clearly allow persons of skill in the art to recognize the Applicants are in possession of the claimed subject matter. While arguments regarding the compounds are deemed persuasive, arguments reading on variants of SEQ ID NO: 6 have been carefully considered, but found unpersuasive.

9. The written description is not commensurate in scope with these method claims including variants and mutants of SEQ ID NO: 6. Applicants' specification inadequately describe or evidence FANCA nucleic acids and polypeptides that are variants, mutants and homologs. Applicants seem to only be in possession of a FANCA nucleic acid and FANCA polypeptide that are identified as SEQ ID NO: 5 and SEQ ID NO: 6, respectively.

10. The skilled artisan cannot envision the detailed structure of variants embraced by amino acid sequences at least 95% identical to SEQ ID NO: 6 or FANCA and conception is not achieved until reduction to practice has occurred, see page 19 of the specification. Adequate written description requires more than a mere statement that it

is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not fully described species, mutants and variants embraced by the term FANCA with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel,* 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.,* 18 USPQ2d 1016.

Accordingly, for the reasons of record and set forth herein the rejection is maintained.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The rejection of claim 23 under 35 U.S.C. 102(a) as being anticipated by Folias et al. is maintained.

13. Claim 23, is drawn to a method that has 2 active steps: (1) contacting a compound with Fanconi anemia group A protein (FANCA) polypeptide with 95% identity to SEQ ID NO:6 and (2) determining the effect of the compound upon the FANCA polypeptide as compared to a control without the compound. "Effect" is defined in the specifications (p. 21) and is recited as such in Applicants' response p.11 filed on

08/02/2007 as changes in a characteristic of a FANCA polypeptide, e.g., changes in ligand or substrate binding activity"

14. Folias et al. teaches that contacting FANCA with BRCA1 results in ligand binding; therefore Folias et al. teaches the same active steps as applicant's claimed method. As evidence by the specification the "effect" being determined is ligand binding of the test compound, BRCA1, to the FANCA polypeptide. Applicant argues that the reference does not teach the limitation of comparing the "effect" with the test compound to the "effect" of a control assay without the test compound. This argument is not found persuasive. One of ordinary skill in the art would readily envisage that the "effect", as defined by the specification, of FANCA without the test compound, as in a control assay, would result in no ligand binding of BRCA1 to FANCA and thus a change in the "effect", defined as ligand binding of the FANCA polypeptide to BRCA1, would occur. The reference teaches each and every limitation of the claims and the rejection is therefore maintained.

15. The rejection of claim 23 under 35 U.S.C. 102(b) as being anticipated by McMahon et al. is maintained.

16. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by McMahon et al. (J. of Biol. Chem. 1999) as evidence by the specification. Claim 23 is drawn to a method that has 2 active steps: (1) contacting a compound with Fanconi anemia group A protein (FANCA) polypeptide with 95% identity to SEQ ID NO:6 and (2) determining the physical effect of the compound upon the FANCA polypeptide. "Effect" is defined in

the specifications (p. 21) and is recited as such in Applicants' response on p.11 filed on 08/02/2007 as "changes in a characteristic of a FANCA polypeptide, e.g., changes in ligand or substrate binding activity".

17. McMahon et al. teaches that contacting FANCA with alpha Spectrin II results in ligand binding; therefore McMahon et al. teaches the same active steps as applicant's claimed method. As evidence by the specification the "effect" being determined is ligand binding of the test compound, alpha Spectrin II, to the FANCA polypeptide. Applicant argues that the reference does not teach the limitation of comparing the "effect" with the test compound to the "effect" of a control assay without the test compound. This argument is not found persuasive. One of ordinary skill in the art would readily envisage that the "effect", as defined by the specification, of FANCA without the test compound, as in a control assay, would result in no ligand binding of alpha Spectrin II to FANCA and thus a change in the "effect", defined as ligand binding of the FANCA polypeptide to alpha Spectrin II, would occur. The reference teaches each and every limitation of the claims and the rejection is therefore maintained.

## *New Grounds of Rejection*

### *Claim Rejections - 35 USC § 112*

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 23 and dependent claims 36-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Claim 23 recites, "wherein *inhibition* of the FANCA polypeptide in a cell causes cell cycle arrest". It is unclear what is meant by "inhibition". Does Applicant refer to "inhibition" of the FANCA polypeptide to mean inhibition of the FANCA polypeptide to bind to its ligand, inhibition of the protein expression of the FANCA polypeptide, inhibition of a substrate to bind to the FANCA polypeptide, etc? Clarification is required.

***Conclusion***

21. Claims 23 and 36-41, 43 and 44 are rejected.

22. Claim 42 is objected to for depending from a rejected claim.

23. No claim is allowed

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER